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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,597	04/28/2000	Timothy E. McAlindon	BU-022XX	4637

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EXAMINER
KAPADIA, MILAN S

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/560,597	MCALINDON ET AL.
	Examiner	Art Unit
	Milan S Kapadia	3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 31 December 2002. Claims 1-38 are pending. Claims 1, 8, 13, 29, and 38 have been amended. Claims 15 and 19 have been canceled.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-14, 16-18, 20-25,l and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al (5,991,731; as cited in the previous Office Action) in view of Hopp (Hopp, David I, "Three topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security," Drug Information Journal, Oct-Dec, 1999; as cited in the previous Office Action).

(A) As per claim 1, Colon teaches a method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

assigning at the primary sight, a unique identifier and a unique log-in password to at least one clinical trial user located at a remote internet site distant from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site (Colon; col. 4, line 54-col. 5, line 24 and col. 7, lines – 65);

accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site (Colon; col. 2, lines 58-63, figure 1, figure 6, and col. 7, lines 8-15) ;

providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form (Colon; col. 7, lines 8-18 and figure 6; it is respectfully submitted that "question and answer selection" is a known form of "inputting patient data & events"); and

compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial (Colon; col. 7, line 46-col. 8, line 5).

Colon fails to expressly teach providing to the clinical trial user, responsive to the receipt by the primary site of the unique identifier and the unique log-in password, instructions on using the test substance and also fails to expressly teach the clinical trial user as a clinical trial participant. However, this feature is old and well known in the art, as evidenced by Hopp's teachings with regards to this limitation. In particular, Hopp teaches the use of the Internet for clinical trials and teaches documents, such as contracts, informed consent forms, and study procedure manuals, shared with clinical trial participants for viewing and printing (Hopp; page 4, paragraphs 1-2; it is respectfully submitted that "instruction on using the test substance" is met by "study procedure manuals.") Furthermore, Hopp also teaches that a clinical trial participant's access to the system is confidential and controlled (Hopp; page 3, paragraphs 7-11; it is respectfully submitted, that it is well-known for a confidential and controlled access to a system to be based on a unique user identifier and password as shown above by Colon and incorporated herein). It is respectfully submitted, that it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the system taught by Colon with Hopp's teaching with regards to this limitation, with the motivation of making information available in a more timely way to clinical trial participants (Hopp; page 3, paragraph 1).

(B) Claims 2-7 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 3), and incorporated herein.

(C) Claim 8 differs from the features of claims 1, 2, 5, and 7 by reciting "after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity and eligibility of the candidate to participate." Colon teaches the information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate (Colon; col. 6, line 39-col. 7, line 7). The combined system of Colon and Hopp collectively fail to expressly teach that the "information transfer" occurs after the receipt of the candidate's informed consent by at least one investigator. However, as shown above in rejection of claim 6, it is in the interest of a study investigator to verify and maintain a copy of the consent form in order to determine the accuracy and reliability of study results, as such it would have been obvious, to one having ordinary skill in the art at the time the invention was made, to expand the collective system taught by Colon and Hopp to perform "information transfer" after the receipt of the candidate's informed consent by at least one investigator, with the motivation of enabling the investigator to verify and keep a copy of the consent form for recording purposes prior to informing the participant of their status. The remaining features of claim 8 repeat features of claims 1, 2, 5, and 7 and are therefore rejected for the same reasons given above in the rejection of claims 1, 2, 5, and 7 and incorporated herein.

(D) Claims 9-12 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 3), and incorporated herein.

(E) As per claim 13, Colon teaches collecting and storing at a secure site, which is the primary site, accessible by the at least one investigator and by the participant, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator (Colon; col. 7, lines 46-61).

(F) Claims 14, 16-18, 20-25, and 28 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 3), and incorporated herein.

(G) System claim 29 repeats the subject matter of method claim 1 as a set of apparatus elements rather than a series of steps. As the underlying processes of claim 1 has been shown to be fully disclosed by the collective teachings of Colon and Hopp in the above rejections of claim 1, it is readily apparent that the system disclosed collectively by Colon and Hopp includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 1, and incorporated herein.

(H) Claims 30-37 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 3), and incorporated herein.

(I) System claim 38 repeats the subject matter of method claim 13 as a set of apparatus elements rather than a series of steps. As the underlying processes of claim 13 has been shown to be fully disclosed by the collective teachings of Colon and Hopp in the above rejections of claim 1, it is readily apparent that the system disclosed collectively by Colon and Hopp includes the apparatus to perform these functions. As such, these limitations are rejected for the same reasons given above for method claim 13, and incorporated herein.

4. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colon et al (5,991,731) and Hopp (Hopp, David I, "Three topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security," Drug Information Journal, Oct-Dec, 1999.) as applied to claims 24 and 25 and further in view of Brin (Brin, Dinah, "Lilly warns Nutri System about using Prozac," The Patriot Ledger, September 17, 1997, pages 5-6) .

(A) Claims 26 and 27 have not been amended and are rejected for the same reasons given in the previous Office Action (paper number 3), and incorporated herein.

Response to Arguments

5. Applicant's arguments with respect to amended claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

(A) At pages 12-17 of the 12/31/02 communication, Applicant argues each of the applied references individually.

In response, the Examiner respectfully submits that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In particular, the teachings that Applicant argues are missing from the Colon reference are in fact clearly disclosed by the teachings of Hopp and Brin, as discussed in detail within a prior Office Action (paper number 3) and in the preceding rejections, and incorporated herein.

Further, the features newly added and entered in the amendment filed 12/31/02, they have been shown to be fully disclosed by Colon, Hopp, and Brin, as discussed above in detail within the preceding sections of the present Office Action.

In addition, it is respectfully submitted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

6. Applicant's arguments filed 12/31/02 have been fully considered but they are not persuasive. Applicant's arguments will be addressed herein below in the order in which they appear in the response filed 12/31/02.

Affidavit

7. Applicant has submitted an affidavit to remove Hopp (Hopp, David I, "Three topics integral to the use of the Internet for clinical trials: Connectivity, communication, and security," Drug Information Journal, Oct-Dec, 1999.) as a reference applied under 35 U.S.C. § 103 in the previous Office Action. The declaration filed on 12/31/02 under 37 C.F.R. § 1.131 has been considered but is ineffective to overcome the Hopp reference for the following reasons:

(i) The evidence submitted is insufficient to establish a conception of the invention prior to the effective date of the Hopp reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See Mergenthaler v. Scudder, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). In the instant case, there is no clear nexus that ties the clinical science grant application to the subject matter of the instant claims. The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed

genus), in the sense that the claim as a whole reads on it. In re Tanczyn, 347 F.2d 830, 146 USPQ 298 (CCPA 1965)

(ii)The evidence submitted is insufficient to establish diligence from a date prior to the date of reduction to practice of the Hopp reference to either a constructive reduction to practice or an actual reduction to practice. Where conception occurs prior to the date of the reference, but reduction to practice is afterward, it is not enough merely to allege that applicant or patent owner had been diligent. Ex parte Hunter, 1889 C.D. 218, 49 O.G. 733 (Comm'r Pat. 1889). Rather, applicant must show evidence of facts establishing diligence (See MPEP § 715.07(a)).

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Milan S Kapadia whose telephone number is 703-305-3887. The examiner can normally be reached on Monday through Thursday, 8:30 A.M. to 6:00 P.M. In addition the examiner can be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

mk

DINH X. NGUYEN
PRIMARY EXAMINER

February 26, 2003